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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/795,933	03/08/2004	Jan Zavada	D-0021.2-2	2689

24988 7590 02/15/2006

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EXAMINER	
ASHEN, JON BENJAMIN	

ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 02/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/795,933	ZAVADA ET AL.	
	Examiner	Art Unit	
	Jon B. Ashen	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 31-55 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 31-55 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 31-35, and 53-55, drawn to an MN antisense construct that comprises antisense oligonucleotide sequence complementary to SEQ ID NO: 5 or SEQ ID NO: 1, classified in class 536, subclass 24.5 (*This group is further restricted below*).

II. Claims 39-40, drawn to a method of treatment comprising administering the MN antisense construct that comprises antisense oligonucleotide sequence complementary to SEQ ID NO: 5, classified in class 514, subclass 44.

III. Claims 41-52, drawn to an antibody which specifically binds an MN protein or polypeptide, classifiable in class 530, subclass 387.1+ (*This group is further restricted below*).

The inventions are distinct, each from the other because of the following reasons:

Inventions of groups I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different

process of using that product (MPEP § 806.05(h)). The invention of group I is drawn to an MN antisense construct that comprises antisense oligonucleotide sequence complementary to SEQ ID NO: 5 or SEQ ID NO: 1. The invention of group II is drawn to a method of treatment comprising administration of an MN antisense construct that comprises antisense oligonucleotide sequence complementary to SEQ ID NO: 5 or SEQ ID NO: 1. In the instant case, the product as claimed can be used in a materially different process of using that product which would be an in vitro (cell-free) method of making a hybridization probe.

Furthermore, searching the inventions of groups I and II together would impose a serious and undue burden. In the instant case, prior art searches of the composition and of a method of treatment would not be coextensive. Search of each of these inventions would require different key word searches of the composition and the method and would include, at least, a search for the distinctive steps required by the method that would not be required by the composition. These searches would need to be performed in divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious and undue burden on the Office in terms of both search and examination. As such, it would be burdensome to perform a search and examination of the inventions of groups I and II together.

2. Inventions of groups I and II and group III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have

different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The inventions set forth in groups I and II are relied upon as above. The invention set forth in group III is drawn to an antibody that specifically binds an MN protein or polypeptide. In the instant case the different inventions are not disclosed as capable of use together and have different modes of operation. An antisense oligonucleotide operates by hybridization to a complementary nucleic acid molecule. A method of treatment operates by the particular steps required by administration of a specified therapeutic agent, in this case, an antisense oligonucleotide. An antibody operates to bind to a specific site on a protein by epitope recognition.

Furthermore, searching any of the inventions of groups I-III together would impose a serious search burden. In the instant case, prior art searches of each composition and of the method would not be coextensive. Search of each of these inventions would require different key word searches in divergent patent and non-patent literature databases and would require, at least, a search for particular limitations required by each composition that are not required by a search for the other and a search for distinct steps required by the method that would not be required by a search of the compositions. Each search would then require subsequent in-depth analysis of all relevant prior art literature, placing an undue and serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform search and examination of any of the inventions set forth in groups I-III.

3. Group I is further restricted as follows:

4. Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the antisense sequences listed in claims 31, 33 and 55 are subject to restriction. The Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such nucleotide sequences to be claimed in a single application. Under this policy, up to 10 of independent and distinct nucleotide sequences will be examined in a single application. (see MPEP 803.04 and 2434)

Claims 31, 33 and 55 are subject to an additional restriction since the nucleotide sequences claimed are not considered to be a proper genus/Markush. See MPEP 803.02 - PRACTICE RE MARKUSH-TYPE CLAIMS - If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in In re Weber, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and In re Haas, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. In re Harnish, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Claims 31 and 33 specifically claim antisense oligonucleotides that are complementary to SEQ ID NO: 5 and 1, respectively wherein those sequences can be one of SEQ ID NO: 3, 4 or 7, as listed in claim 55. In the instant case, although the antisense sequences claimed each target and modulate expression of a MN gene, the instant antisense sequences are considered to be unrelated, since each antisense sequence claimed is structurally and functionally independent and distinct for the following reasons: each antisense sequence has a unique nucleotide sequence, each antisense sequence targets a different and specific region of an MN nucleic acid, and absent evidence to the contrary, each antisense, upon binding to an MN nucleic acid, is expected to functionally modulate (increase or decrease) the expression of MN to varying degrees. As such the Markush/genus of antisense nucleotide sequences in claims 31, 33 and 55 are not considered to constitute a proper genus, and are therefore subject to restriction.

Furthermore, a search of more than one (1) of the antisense sequences claimed in claims 31, 33 and 55 presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed antisense sequences. MPEP 808.02 states in part: Where the related inventions as claimed are shown to be distinct under the criteria of MPEP 806.05(C) - 806.05(i), the examiner, in order to establish reasons for insisting upon restriction, must shown by appropriate explanation one of the following:

(C) A different field of search: Where it is necessary to search for one of the distinct subjects in places where no pertinent art to the other subject exists, a different field of search is shown, even though the two are classified together.

It is noted that a search of the available sequence databases produces a listing of references disclosing the sequence most similar to the query sequence. This is the "place" where the examiner searches for prior art. The prior art relating to another query sequence will not be found in this "place"- a different listing of references must be generated and searched by the examiner. Thus a different search is shown, and restriction is proper.

In view of the foregoing, one (1) antisense sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicant is required to elect either one (1) antisense sequence from claim 55 that that corresponds with a target nucleotide sequence that is SEQ ID NO: 5 or SEQ ID NO: 1, from claims 31 and 33, respectively. Note that this is not a species election.

5. Group III is further restricted as follows: Claims 47-52 are subject to an additional restriction since the amino acid epitope sequences claimed are not considered to be a proper genus/Markush. See MPEP 803.02 - PRACTICE RE MARKUSH-TYPE CLAIMS - If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In

such a case, the examiner will not follow the procedure described below and will not require restriction. Since the decisions in In re Weber, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and In re Haas, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. In re Harnish, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature disclosed as being essential to that utility.

Claims 47-52 specifically claim antibodies that specifically bind an MN antigen epitope selected from the group consisting of amino acid sequences: SEQ ID NO: 10-16. In the instant case, although the MN antigen epitope amino acid sequences claimed are each a portion of an MN polypeptide, the instant antibodies claimed are considered to be unrelated, since each antibody claimed is structurally and functionally independent and distinct for the following reasons: each antibody has a unique conformation and binding specificity for a particular MN antigen epitope amino acid sequence as claimed, each antibody binds a different and specific antigen of an MN polypeptide, and absent evidence to the contrary, each antibody, upon binding to an MN polypeptide, is expected to functionally modulate (increase or decrease) the activity of MN to varying degrees. As such the Markush/genus of MN antigen epitope amino acid sequences in claims 47-52 are not considered to constitute a proper genus, and are therefore subject to restriction.

In view of the foregoing, one (1) MN antigen epitope amino acid sequence as set forth in claims 47-52 is considered to be a reasonable number of MN antigen epitope amino acid sequences for examination. Accordingly, applicant is required to elect either one (1) MN antigen epitope amino acid sequence from claims 47-52. Note that this is not a species election.

6. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and would require divergent searches of sequence and literature databases placing an undue administrative burden on the examiner, restriction for examination purposes as indicated is proper.

7. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon B. Ashen whose telephone number is 571-272-2913. The examiner can normally be reached on 7:30 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Andrew Wang can be reached on 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jba

J.D. SCHULTZ, Ph.D.
PATENT EXAMINER